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| APPLICATION NO.              | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|----------------|----------------------|---------------------|------------------|
| 08/928,272                   | 09/12/1997     | MICHAEL J. ISKRA     | P-3818              | 9434             |
| 7:                           | 590 12/13/2005 |                      | EXAM                | INER             |
| RICHARD J                    | RODRICK        |                      | PATEL, N            | IITAL B          |
| BECTON DICKINSON AND COMPANY |                |                      |                     |                  |
| 1 BECTON DRIVE               |                |                      | ART UNIT            | PAPER NUMBER     |
| FRANKLIN LAKES, NJ 074171880 |                | 3743                 |                     |                  |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | <del>-</del>  |   |  |  |  |  |  |
|---|---|---|--|--|--|--|--|
| •   | Application No.   | Applicant(s)  |  |  |  |  |  |
| <b></b>   | 08/928,272  | ISKRA, MICHAEL J.   |  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |  |  |  |  |  |
|   | Mital B. Patel  | 3743  |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |   |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N.<br>nely filed<br>I the mailing date of this communication.<br>ED (35 U.S.C.§ 133). |  |  |  |  |  |
| Status  |   |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 11 N   | ovember 2005.   |   |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  | ☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.   |   |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |   |  |  |  |  |  |
| closed in accordance with the practice under E  | Ex parte Quayle, 1935 C.D. 11, 4  | 53 O.G. 213.  |  |  |  |  |  |
| Disposition of Claims   |   |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1,5-9,19 and 20</u> is/are pending in the   | application.  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1,5-9,19-20</u> is/are rejected.  |   |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |   |  |  |  |  |  |
| Application Papers  |   |   |  |  |  |  |  |
| 9) The specification is objected to by the Examine  | er.   |   |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |   |  |  |  |  |  |
| Applicant may not request that any objection to the   | drawing(s) be held in abeyance. Se  | e 37 CFR 1.85(a).   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |   |  |  |  |  |  |
| 11) ☐ The oath or declaration is objected to by the Ex  | kaminer. Note the attached Office   | Action or form PTO-152.   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |   |  |  |  |  |  |
| Attachment(s)  1) \( \bigcap \) Notice of References Cited (PTO-892)  2) \( \bigcap \) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4) ☐ Interview Summary<br>Paper No(s)/Mail D  |   |  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date  |   | Patent Application (PTO-152)  |  |  |  |  |  |

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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/05 has been entered.

### Response to Arguments

2. Applicant's arguments filed 11/11/05 have been fully considered but they are not persuasive.

## Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

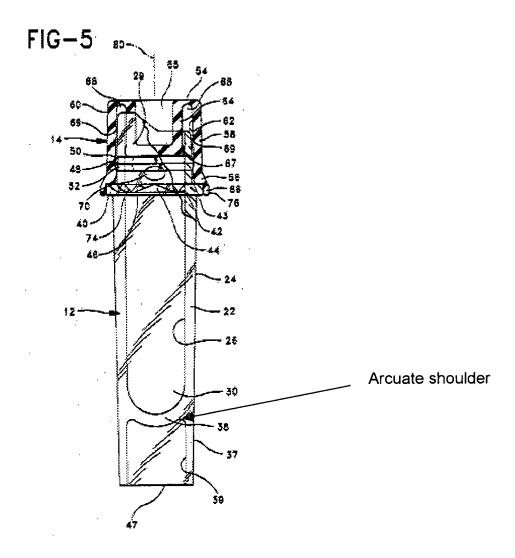
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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- 4. Claims 1, 5, 7, 8, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns (US 5458854).
- 5. As to claim 1, Burns teaches a one-piece collection container assembly comprising an elongate tubular housing having opposed first and second ends; and a solid partition 38 positioned within the housing between the first and second ends; the housing defining a volume for specimen collection therein between the first end and the partition; the second end comprising a bottom end below said partition, the bottom end comprising an annular skirt at 47 and a semi-spherical bottom at 38. Please note that the Examiner maintains that Burns teaches a rounded bottom (See Fig. 1 which depicts the bottom to be rounded).

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- 6. As to claim 5, Burns teaches an assembly wherein the partition is arcuate in shape to provide the volume for specimen collection with at least a partially rounded bottom portion.
- 7. As to claim 7, Burns teaches an assembly wherein the housing is a thermoplastic polymer.
- 8. As to claim 8, Burns teaches an assembly wherein the thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene napthalate, polyvinyl chloride or copolymers thereof.

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### Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns.
- 11. As to claim 6, Burns fails to specifically teach an assembly wherein the partition is conical in shape. However, the shape of the partition is a mere design choice that can be obtained through routine observation and experimentation. Furthermore, the Applicant fails to disclose why one particular shape would be advantages over another or what particular purpose is served by a conical shaped partition or how the specific shape provides an unexpected result and therefore, it would be obvious to one of ordinary skill in the art to make the partition of any desired shaped absent criticality.
- 12. As to claim 9, Burns fails to specifically teach an assembly wherein the housing has the particular dimensions as set forth by the claim. However, the Applicant fails to disclose why those particular dimensions are advantageous or what particular problem those specific dimensions solve. Furthermore, depending on the intended use, e.g., how much sample is to be collected, the dimensions of the housing will vary and such dimensions may also be derived

through routine observation and experimentation and therefore, it would be obvious to one of ordinary skill in the art to make the housing of any desired dimensions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel Primary Examiner Art Unit 3743

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